

**BEFORE THE UNITED STATES DEPARTMENT
OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE**

In the Matter of	: Docket Nos.:
	:
Milk In The Northeast	: AO-14-A73, et al;
	:
Marketing Area, et al	: DA-03-10

**COMMENTS UPON RECOMMENDED DECISION OF DAIRY FARMERS OF
AMERICA, INC., O-AT-KA MILK PRODUCTS COOPERATIVE, INC., UPSTATE
FARMS COOPERATIVE, INC. AND DAIRYLEA COOPERATIVE INC.**

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I. INTRODUCTION

_____These comments are filed on behalf of DFA, O-AT-KA, Upstate, and Dairylea in response to the Recommended Decision which was published at 71 Fed. Reg. 28590 (May 17, 2006).

DFA, O-AT-KA, Upstate, and Dairylea strongly support the important advance in defining fluid milk products which is embodied in the Recommended Decision's adoption of the 2.25% true protein standard. This brings the federal order system's definition of Class I fluid milk products into line with the marketplace and with current technology. The Recommended Decision's recognition of the primary importance of protein as an ingredient in fluid milk products is crucial and to be commended. In addition, and perhaps of equal importance, is the determination to count all nonfat dairy ingredients in defining fluid milk products. This provides an important and clear baseline to the protein level determination. Further, we support and endorse the Recommended Decision's pricing of milk protein concentrates (MPCs) in fluid milk products. This goes a distance toward closing a gap in fluid milk ingredient pricing which exists pursuant to current administrative practice. In these and all other respects (except as noted hereafter), O-AT-KA, Upstate, Dairylea and DFA join and endorse, the separately-filed comments of the National Milk Producers Federation submitted by Roger Cryan.

These comments will address three issues: (1) the need to uniformly price all proteins in fluid milk products; (2) the need to have a definitive minimum ingredient standard for fluid milk products; and (3) the need to retain the current language concerning products especially prepared for infant feeding and dietary use (meal replacement) packaged in hermetically sealed containers.

II. ALL MILK PROTEIN AND NONFAT SOLIDS IN FLUID MILK PRODUCTS SHOULD BE PRICED

DFA, O-AT-KA, Upstate, and Dairylea request that the Department reconsider the Recommended Decision's determination that nonfat dry milk and MPCs, but not casein or whey, be priced in fluid milk products.¹ The Recommended Decision states:

Because casein, calcium and sodium caseinates and whey are milk-derived, they are recommended to be included in determining if a product is a fluid milk product. However, their use in fluid milk products will not be priced at the Class I price or be subject to an "upcharge" as will non-fat dry milk and MPC.

71 Fed. Reg. at 28601 col. 2.

We suggest that all milk-derived ingredients in fluid milk products should be uniformly priced. We believe there are several very important reasons which support our position.

1. Fractionation technology makes any distinctions outmoded. As the

Recommended Decision found (quite ironically in this context):

[T]he ability to separate proteins from the lactose and ash and to separate proteins between casein and "whey proteins" creates the opportunity to make new dairy-based beverages that may be similar to milk but are different in composition.

71 Fed. Reg. at 28600, col. 2. We agree with this statement in the Recommended Decision. It is indisputably correct and the pricing of milk solids in fluid milk products should follow the technology.

While noting this technological advance, the Recommended Decision nevertheless continues to allow fractionation to determine pricing with the following less-than-overwhelming

¹ On this issue, DFA, O-AT-KA, Upstate, and Dairylea's position differs from that of NMPF which supports the pricing of casein, but not whey proteins.

rationale:

These products [casein and whey] cannot readily be substituted for a listed fluid milk product as can nonfat dry milk and MPC. For example, whey contains little or no casein and only some of the lactose or ash of milk. Similarly, calcium and sodium caseinates do not contain the whey protein Therefore these and similar milk-derived ingredients will not be priced. . . .

71 Fed. Reg. at 28601, col. 2.

We frankly cannot follow this logic for support of a pricing distinction. The rationale is tautologous when it says “Casein and whey cannot be substituted [separately] for a fluid milk product containing both ingredients. . . . Casein [since it has been fractionated from whey] does not contain whey.” Using the same analysis, one would have to acknowledge that MPCs which, as their name indicates, concentrate the milk protein and contain reduced lactose, therefore, cannot be substituted for NFDM which is more than 50% lactose. MPCs will, however, now be priced, correctly we believe, on the same basis as NFDM which does contain lactose. But, under the Recommended Decision, casein and whey, which have in essence the same compositional relationship to MPCs (which combine the two) as MPCs do to NFDM, will be priced.² We believe the same pricing principles which led the Recommended Decision to price MPCs should lead to the pricing of casein and whey on the same basis.

The Recommended Decision’s non-uniform pricing of the same ingredients leads to this result: an enterprising handler can acquire, separately, whey proteins, casein, lactose, and calcium – all the ingredients in nonfat milk solids – add water and have a beverage identical (or nearly

² Left open seems to be the academic question of whether fractionated lactose is priced. It is an academic question because with milk equivalent conversion on a protein basis, lactose would not add pricing volume to a fluid milk product. But the question itself emphasizes the inscrutable basis upon which the Recommended Decision finds that some components should be priced, while others should not.

identical) to fresh milk in components and it would not be priced as a Class I fluid milk product. This surely is not the result supported by the record of this hearing.

2. Pricing differences for identical ingredients will drive product formulation and use. NFDM and MPCs both contain milk proteins -- casein and whey. When those proteins are priced in NFDM and MPCs, but not in isolated formulations -- caseinates, whey protein isolates, etc. -- an economic incentive is created to use the lower priced ingredients. This is a great concern for any and all current producers of MPCs or NFDM or processors of fluid milk products using MPCs or NFDM, many of which are now domestically produced. These products will, under the Recommended Decision, now be at an economic disadvantage with caseinates which are primarily imported. Future products, new product development, and current products will now be tilted toward use of the non-priced ingredients. The bottom line is that for dairy producers the same end product -- a Class I fluid milk product, a milk beverage -- will have different returns solely on the basis of the degree of fractionation of the protein ingredients; and for processors, some forms of identical ingredients will be favored over others.

We are convinced that all dairy protein ingredients should be uniformly priced in FMPs. This includes whey protein from any source -- whether the by-product of cheese-making³ or a product of raw milk fractionation. Anything less than uniformity of ingredient pricing will skew the marketplace for the ingredients, tilting it one way or another, and for no compelling reason so

³ DFA, DairyIea, O-AT-KA, and Upstate are abandoning the position taken at the hearing and in post-hearing briefs that whey from cheesemaking should not be priced while whey proteins derived from raw milk fractionation should be priced. We believe that it makes most sense from a policy and competitive perspective for all dairy protein in fluid milk products, from whatever source, to be priced. Furthermore, technological advances in processing whey protein from cheesemaking are allowing manufacturers to tout whey protein as having functional benefits in pasteurized and retorted beverages - see e.g., <http://www.leprinofoods.com/whey/pdfs/TempPro80.pdf>.

far as we can determine.

III. THE DEFINITION OF FLUID MILK PRODUCTS SHOULD HAVE FIRM COMPOSITIONAL MINIMUMS

DFA, O-AT-KA, Upstate, and Dairylea also request reconsideration of the lack of a “hard bottom” for the compositional standard provisions as proposed in the Recommended Decision. If the language remains as currently written, it will tend to lend credence to the critics of Order regulation who say that Federal Order provisions stifle product innovation. If the Recommended Decision is left unchanged, these critics may very well have a point.

The current criteria for defining a fluid milk product provide important guidance to the industry. In addition to the actual wording, the format for the provisions further clarifies the guidance needed to develop new products.

Presently, Section 1000.15 (a) sets out initially that every milk product in fluid or frozen form containing less than 9% butterfat *is* a fluid milk product (FMP) if it is intended to be used as a beverage. This establishes the concept that “form and use” is the over-arching guideline for classification. However clear that may seem, in reality there need to be additional qualifiers for the FMP definition because of the diversity of dairy products.

Thus, the regulations further refine the classification by first enumerating all the products that knowledgeable persons in the industry would commonly recognize, by product name, which *are* fluid milk products. The next step in the process is to define, again by product name, those familiarly known products which may be fluid in nature but are not intended to be beverages, instead fitting other criteria that can be easily recognized, and thus these products *are not* fluid milk products. This process of classification by explicit inclusion and specific exclusion is both logical and sensible.

However, one more step is needed in order to firmly establish a useful level of specificity. The compositional standards make clear to the industry what will be the final classification of any product that may still be in the “unknown” category. If there are new products or product extensions which are the result of new technology, the compositional standards answer the question: what classification will the product have? The compositional standard is the last line of definition – if the other provisions are not clear this provision provides clarity and a definite conclusion.

The lack of a “hard bottom” at the end of the compositional standards of the definition as proposed in the Recommended Decision leaves the dairy formulation industry in a compromised and untenable position. It cannot work with a potential customer and/or new product because product classification cannot definitively be determined and product cost therefore cannot be readily computed. The rationale for why a product may or may not be a fluid milk product is no longer objective.⁴ The potential new product developer has no clear way to understand what the rules for product development are and the entire industry becomes much more open to the potential for litigation. Potential beverage customers will look to other non-dairy component suppliers for a more predictably-priced product.

In this scenario, the Department will always be on the defensive and in a lose-lose

⁴ If there is any thought that industry concerns for predictability of classification of new products are not reasonable, and that “form and use” is a sufficient test, we submit the following blind-panel test on classifying new products: Take two beverage products, and assume that neither currently has a classification and that both would be submitted for determination pursuant to the “form and use,” no-bright-lines criterion: Both products are beverages. One product is sold in the dairy case, is perishable, and has appeal to consumers of all ages, sexes and demographics; the other product is supplied in a can, is not perishable and is shelf stable at ambient temperatures, is milk protein-based, marketed primarily through health food specialty stores and used almost exclusively by body builders. The first product is liquid yogurt; the second is a high-protein drink. When submitted on the “form and use” test, which product will be Class I, and which product Class II?

position – any decision will be viewed as subjective and one party a financial winner and the other a financial loser. Every classification decision will be viewed as biased and the Department will spend more resources on product classification issues than is needed. When new products actually make it through the development stage, the marketers will have to wait on the Department for a ruling on classification – which will likely be controversial, will necessarily slow the process of getting the product to market, and inevitably invite the input of outside-USDA influences in the ad hoc classification decision.

We would prefer that the compositional standard of 2.25% true protein by weight be a “hard bottom” subject to no further discretion. If processing technology changes such that new provisions and standards are needed then a new hearing can and should be called to consider necessary updating of the order language at that time. Such updating is what this rulemaking is about and, while there are complaints about change – as there almost inevitably are – the Secretary has clear legal authority to hold hearings and make regulatory changes which are supported by a hearing record. The new product maker(s), if affected by proposed new actions, will have an open and full opportunity to make their case, and all others interested will have the same opportunity as well.

If the Department believes it is appropriate that it have open-ended “form and use” classification authority, it should have submitted such a proposal in the Hearing Notice. Proposals from the Department are, of course, allowable and have been reflected, for example just since 2000, in proposals made by Market Administrators to amend payment terms and administrative fees in various orders. We are certain if such a clearly set-out proposal had been made in this proceeding the industry would have uniformly opposed the lack of a clear measurable standard.

At a minimum, in our view the Department should withhold a final determination on this aspect of the decision, and reopen the hearing to take evidence on this element of the proposed regulation. The proposal could be published, and would need to be supported and defended on the record in the same manner as all proposals. Comments and additional proposals (on the same subject) could be heard as well.

IV. THE EXEMPTION FOR FORMULAS ESPECIALLY PREPARED FOR INFANT FEEDING AND DIETARY USE (MEAL REPLACEMENT) PACKAGED IN HERMETICALLY SEALED CONTAINERS SHOULD NOT BE CHANGED.

The exemption of formulas especially prepared for infant feeding and dietary use (meal replacement) and packaged in hermetically sealed containers has been a longstanding aspect of the fluid milk product definition. Past decisions have supported this exemption and marketers have relied upon the exemption for developing and marketing specialty formulations in retorted long shelf life containers. DFA, O-AT-KA, Upstate, and Dairylea request that the Department reconsider the proposed elimination of, or revision of, this exemption.

The witness for O-AT-KA testified extensively on several of these types of products and how they have not been marketed to compete with milk, have not been sold on the dairy shelf, and typically contain a variety of mostly dry dairy ingredients along with an array of other nutrients for specialty formulation (Alexander, Tr. 406-408). Their evolution was in most cases from dried powders to ready-to-drink products as the category developed. They therefore were not sold as “fortified milk” and in fact are not seen as “dairy products” at all but viewed as nutritional meal replacements or supplements for dietary use. The products are designed to meet different needs: meal replacement for dieters, meal replacement or nutrient supplementation for geriatric or pediatric use, or for ready-to-drink high protein shakes for body builders. In tasting

these products, one would have not confuse such beverages with traditional fluid milk products. The O-AT-KA testimony on this exemption was uncontested in the record.

There was no evidence presented in the record by any witness that this exemption should be changed in the fashion proposed by the Department. In fact, the major dairy producer organization, NMPF, supported continuing this exemption, in its present form and interpretation, and has reiterated this in its brief on the Recommended Decision.

The alternative proposal presented by the witness from Hormel did not offer any testimony or evidence to support a change in the current exemption for these products, instead he suggested an additional exemption proposal for “nutrient enhanced fortified formulas especially prepared for the health care industry.” (Tr. p. 1143) In our view, the Hormel proposal should stand on its own. If the Department feels compelled to provide an exemption for “nutrient enhanced fortified formulas especially prepared and sold to the health care industry” (despite concerns that are discussed by NMPF in its brief), this can be done with a separate exemption which does not disrupt the current exemption for infant formula and dietary use products in hermetically sealed containers. Novartis offered a proposal for changes, but did not provide any testimony for the record in support of their proposal, and as it was, that proposal would have greatly broadened the exemption beyond current language, as well.

The current “hermetically sealed” requirement coupled with the “infant formula” and “dietary use” product descriptors provides a superior guideline to distinguish products outside the “competitive sphere” of traditional fluid milk products from those within the sphere than does the Recommended Decision’s adoption of a “sold to” distinction. Classifying, and thus exempting, products on the basis of particular marketing channels raises serious issues of record keeping, tracking and auditing with implications that have not been fully discussed by the

industry.⁵ It is not clear from the Recommended Decision, and certainly not on the record, what it means to “sell to the Health Care Industry” and even what constitutes the “Health Care Industry” to begin with.⁶

As discussed in the NMPF brief, the higher cost of hermetically sealed packaging discourages marketers of traditional fluid products from circumventing Class I pricing. Along with added nutrients and vitamins, the added costs make these products much higher cost than traditional milk products. USDA has previously recognized these costs and the wider area of product distribution. Mr. Alexander for O-AT-KA referred to this passage from the 1993 decision which specifically addressed, in the context of infant formulas and meal replacements, the basis for the existing classification distinction:

“In addition, the cost of extra packaging, and the Class II attributes of having an extended shelf-life and being distributed over a wider area justify Class II classification for hermetically sealed packaging, while fresh product with limited shelf-life should be Class I.”

(Tr. 412, quoting 58 Fed. Reg. at 12659 (March 5, 1993)) This Recommended Decision does not provide a basis for a result that would be contrary to this finding.

⁵ In fact, the pros and cons of the Recommended Decision’s proposal on this point were not discussed at the hearing at all because neither the proposed rule on this issue, nor anything close to it, was promoted by anyone at the hearing. As noted in these comments, the proponents of changes in this aspect of the fluid milk product definition proposed **expanding** the category, not contracting it.

⁶ Ironically, adopting the “sold to the health care industry” test will not solve the problem which the Recommended Decision identifies (71 Fed. Reg. at 28602, col. 2) as leading to the recommended change which is: different classifications for the same product depending on packaging. The marketing channel distinction will mean that the same product sold to a drug store, or grocery store, or convenience store, will have a different classification than when distributed to whatever outlets qualify for the health care industry channel, presumably hospitals and nursing homes, for instance. Furthermore, a new and profitable opportunity for product arbitrage will be created: Health care industry buyers (at Class II prices) will have the opportunity to re-sell or re-distribute the products to Class I outlets, pocketing the price difference or sharing it with the Class I customer. This is surely neither an intended, nor desired, result.

Research and development, and in some cases investments, are being stymied by this Recommended Decision. The adverse affects are being felt at O-AT-KA. O-AT-KA is the largest U.S. producer of high protein ready-to-drink beverages and uses significant amounts of imported casein and milk protein concentrates and some domestic whey protein concentrates. Increases in international protein prices have allowed liquid UF proteins to be competitive with imported casein and milk protein concentrates. As stated in the record, O-AT-KA's goal is to use its own producers' milk to replace the imported proteins.

However, O-AT-KA has placed a hold on a significant capital investment for enhanced milk protein fractionation due to the uncertainties from this decision. Depending on how the Department decides the pricing on these different protein ingredients and the proposed change in the meal replacement exemption, we do not know if our customers will want or need to shift from MPCs to casein, or from casein and MPCs to whey protein, or shift away from dairy ingredients altogether depending on the various scenarios that may come out of the Final Decision. O-AT-KA, Upstate, DFA, and Dairylea are very concerned that the potential cost increases to protein ingredients in this dietary use product category, now exempt, will create significant incentives to formulate away from dairy-derived protein ingredients which, under the Recommended Decision, would be priced at the Class I level. The significant cost of the Class I upcharge will cause other non-dairy ingredients to be used as an alternative over time.

Ironically this Recommended Decision even speaks to the criteria of whether the product in question is comparable to listed products and how:

In this regard if the intended use of the product is a food item that does not compete with fluid milk in the market place, the product should be exempted from the fluid milk product definition.

71 Fed. Reg. at 28601, col. 3.

Therefore, DFA, O-AT-KA, Upstate, and DairyIea strongly object to any changes in the infant formula and dietary use (meal replacement) language and interpretation at this time. There was no evidence in the record that these products compete with fluid milk or that producers and public policy would be better served by such a change. If such issues arise, a hearing can be called to consider any changes. As stated previously, the Department always has the opportunity to suggest a proposal that can be discussed at a hearing.

V. CONCLUSION

DFA, O-AT-KA, Upstate, and DairyIea again wish to note their support for the Recommended Decision's very important adoption of a true-protein based composition test for fluid milk products, and for the accompanying recommendation that all proteins in fluid milk products be considered in the classification equation and that the protein in MPCs be priced in Class I products.

On the basis of this brief, we urge the Department to reconsider three aspects of the decision and (1) price uniformly all milk protein in Class I products; (2) make the compositional criteria for fluid milk products firm, known bright line minimum requirements which will control the classification of such products; and (3) retain the current language which exempts "formulas

especially prepared for infant feeding and dietary use (meal replacement) packaged in hermetically sealed containers ” from the fluid milk product classification.

Respectfully submitted,

Dated: July 17, 2006

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